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MS APPEAL BRIEF - PATENTS
PATENT
1422-0507P

IN THE U.S. PATENT AND TRADEMARK OFFICE

In re application of

Before the Board of Appeals

Makoto OZEKI et al.

Appeal No.:

Appl. No.: 09/980,620 ✓

Group: 1615

Filed: December 5, 2001

Examiner: SHEIKH, H.N.

Conf.: 8140

For: COMPOSITIONS FOR PROMOTING SLEEP

REPLY BRIEF TRANSMITTAL FORM

MS APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

August 3, 2004

Sir:

Transmitted herewith is a Reply Brief (in triplicate) on behalf of the appellants in connection with the above-identified application.

The enclosed document is being transmitted via the Certificate of Mailing provisions of 37 C.F.R. § 1.8.

The Examiner's Answer was mailed on June 3, 2004.

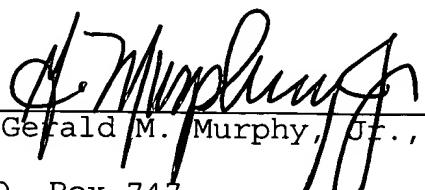
An extension of time under 37 C.F.R. § 1.136(b) to was requested on and was approved on .

Please charge Deposit Account No. 02-2448 in the amount of \$0.00. A triplicate copy of this sheet is attached.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By 
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Attachment(s)

(Rev. 02/12/2004)



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R E P L Y B R I E F

MS APPEAL BRIEF - PATENTS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

August 3, 2004

Sir:

In response to the Examiner's Answer of June 3, 2004, the following remarks are submitted in connection with the above-identified application.

REMARKS

Appellants, herein, provide remarks to rebut some of the Examiner's statements from the Examiner's Answer of June 3, 2004.

On page 9, line 20 to page 10, line 8, the Examiner recites:

Ekanayake et al. is relied upon for the teaching that is known to incorporate various components such as sugars, acid and flavorants in a composition that also contains theanine as a main ingredient. Ample motivation is provided by the art since both references utilize theanine as the active ingredient. Furthermore, Kakuda et al. initially meets the objective of 'sleep promoting' as claimed by Applicants since Kakuda et al. teach that their composition can be suitably taken for people who do not desire to impair their sleep and Kakuda et al. teach counter-acting the effects of caffeine, whereby caffeine is known to hinder sleep. Additionally, it is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. In re Linter, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

Appellants respectfully disagree with the motivation that the Examiner says is provided in the above statement. Appellants respectfully submit that proper motivation cannot be provided simply because theanine is used by two references as an active ingredient.

Appellants respectfully submit that the combination of Kakuda '866 (US Patent No. 5,501,866) and Ekanayake '1628 (US Statutory Invention Registration H1628) cannot be properly combined because Kakuda '866 has as its object the suppression

of the effects of caffeine whereas Ekanayake '1628 has as its object no suppression of the effects of caffeine. Appellants respectfully point out that one of ordinary skill in the art looking to solve the problems disclosed by the prior art references would not modify the references as suggested by the Examiner since this would destroy the teachings of the references. Where the Examiner's proposed modification would render the prior art version unsatisfactory for its intended purpose, the proposed combination is improper. Please see *In re Gordon*, 733 F.2d 980, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984); and see also *Ex parte Rosenfeld*, 130 USPQ 113 (POBA 1961). For this reason, the Examiner's motivation is inadequate to combine the references.

The Examiner also draws attention to *In re Linter* when the Examiner states:

Additionally, it is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. In re Linter, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

Appellants never remotely advanced the idea that the combination of Kakuda '866 and Ekanayake '1628 were combined (by the Examiner) to achieve the same advantage or result discovered by Appellants. Rather, Appellants advanced the idea that Kakuda '866 and Ekanayake '1628 could not be combined because they are incompatible with each other. As mentioned above, and as argued

in the appeal brief, Kakuda '866 has as its object the suppression of the effects of caffeine whereas Ekanayake '1628 has as its object no suppression of the effects of caffeine. These objects are incompatible. Please see page 11, lines 14-25 in the appeal brief.

Appellants respectfully point out that the correct standard to apply is stated in *Linter*, which recites:

In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the references before him to make the proposed substitution, combination or other modification. Id. at USPQ 562.

Thus, the proper standard for combining references, i.e., Kakuda '866 and Ekanayake '1628, is whether or not one would combine them given the reference teachings when they are present together in front of the Examiner. Appellants submit that one of ordinary skill in the art would not combine the references given their teachings. Kakuda '866 and Ekanayake '1628 have opposite objectives for their inventions. Kakuda '866 uses theanine as the active ingredient to suppress the effects of caffeine whereas Ekanayake '1628 uses theanine in its composition because theanine is taught not to suppress the effects of caffeine. Thus, Appellants submit that if one were attempting to suppress the effects of caffeine in one instance, one would certainly not add additional components from a

composition that was known not to suppress the effects of caffeine. In other words, because Kakuda '866 and Ekanayake '1628 have opposite and incompatible objectives, Appellants submit that the motivation for combining them is not present.

Appellants also take issue to the Examiner's use of *In re Aller*, 220 F.2d 454, 105 USPQ 233 (CCPA 1955) in the Examiner's Answer. The Examiner states:

Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). *The prior art teaches that the amount of theanine can be varied (Kakuda et al. col. 6, L. 53-54).* Furthermore, the Examiner notes that instant generic claim 1 is silent as to any amounts of theanine contained in the composition.

Appellants point out that there are many things in this passage with which Appellants disagree.

First, Appellants never remotely suggested that the instant generic claim 1 contained any amounts of theanine in the claim. This is the reason why arguments about amounts of theanine appeared in Group VII (please see page 4, line 14 and page 22, line 1 *et seq.*) Thus, Appellants do agree that claim 1 is silent as to amounts of theanine, but strongly object to the inference by the Examiner that the Appellants argued amounts of theanine regarding generic claim 1.

Second, Appellants attempted to find the passage wherein it is taught in the prior art that the amount of theanine can be

varied. Appellants respectfully point out that there does not appear to be any teaching at column 6, lines 53-54 in Kakuda '866 of varying theanine. Appellants believe that the Examiner may be referring to claim 1 or perhaps to column 2, lines 48-51. This passage recites:

The above-mentioned theanine may be crude theanine or refined theanine, and the theanine content in the caffeine simulation inhibitor is preferably 10 to no more than 500 times the amount of caffeine ingested. (See column 2, lines 48-51 in Kakuda '866).

Appellants first note that the amount of theanine recited in this passage is relative to the amount of caffeine. Thus, little can be inferred unless one happens to also know the amount of caffeine that is imbibed. Appellants submit that these disclosed preferred ranges are often as broad as possible (and often more broad than the effective range) so as to maximize a patentee's scope of protection.

However, as was pointed out in the appeal brief, Appellants believe that it is instructive to look at the mouse experiments so as to determine the preferred range. (See column 3, line 7 to column 4, line 9 in Kakuda '866).

In this regard, the Examiner states at page 16, lines 2-4 of the Examiner's Answer:

Moreover, one of ordinary skill in the art would be entirely capable of determining suitable amounts based on routine experimentation, to obtain the best results possible.

Appellants submit that the Examiner recognizes in this passage that one of ordinary skill would try to determine the best results and not just results that show minimal effectiveness. Using the disclosure of Kakuda '866 (see column 3, line 7 to column 4, line 9 in Kakuda '866), one of ordinary skill in the art would select an amount of theanine that is 1740 mg/kg and not the 174 mg/kg, which was shown to have increased levels of spontaneous movement in the early stages of the experiment (and slight inhibition relative to group B). The minimal response seen at a dosage of 174 mg/kg is very typical of dose dependent responses wherein a small effect is seen at low dosages. However, this dosage is far from the optimal dosage and far from what the data show to be the optimal range in Kakuda '866 of 1740 mg/kg (see column 3, lines 22-28). Thus, Appellants submit that when one uses the optimal dosage as taught by Kakuda '866 (i.e., 1740 mg/kg as shown at column 3, lines 22-28 and at column 4, line 3-5), this in effect teaches away from the claimed amount (in claims 20 and 28) of 0.2 mg/kg to 200 mg/kg.

Third, *In re Aller* is used by the Examiner for the proposition that it only involves routine experimentation to optimize a range. However, Appellants respectfully point out that in *Aller*, it was unknown what was the optimal range for the intended purpose. In *Aller*, there was no teaching of what a preferred amount was. In contrast, one of ordinary skill in the

art reading Kakuda '866 would conclude that a preferred amount is 1740 mg/kg, which is well-outside the instantly claimed range (i.e., 0.2 mg/kg to 200 mg/kg). Appellants point out that this preferred amount teaches away from Appellants claimed range (of 0.2 mg/kg to 200 mg/kg). Thus, if Kakuda '866 is found to be sufficiently close to the instant invention to render it obvious, this leaves open the possibility that discovering the preferred range may not involve only routine experimentation as the Examiner suggests. Consequently, finding this optimal amount may involve parameters that render this optimization different in kind and not merely in degree (please see Aller). Alternatively, Appellants submit that the disclosure of Kakuda '866 is sufficiently remote from the instant invention so as to be unable to render obvious the instant invention.

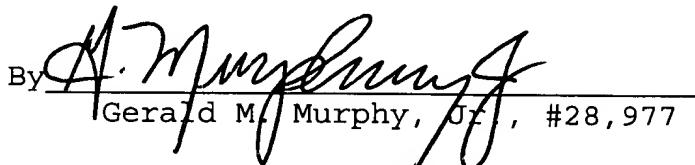
With the above remarks, Appellants believed that the claims, as they now stand, define patentable subject matter such that reversal of the Examiner's rejections is warranted. Accordingly, Appellants respectfully request that the honorable board reverse the Examiner's rejections.

If any questions remain regarding the above matters, please contact Appellants' representative, T. Benjamin Schroeder (Reg. No. 50,990), in the Washington metropolitan area at the phone number listed below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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